DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2014

Siemens Healthcare Diagnostics Inc.
c/o Ms. Fatima Pacheco
511 Benedict Avenue
Tarrytown, NY 10591 USA

Re: k143376
Trade/Device Name: ADVIA Centaur® Progesterone (PRGE) Master Curve Material
ADVIA Centaur® FER Master Curve Material
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Codes: JJX
Dated: November 24, 2014
Received: November 25, 2014

Dear Ms. Pacheco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth A. Stafford -S

for Maria M. Chan, Ph. D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143376

Device Name
ADVIA Centaur® Progesterone Master Curve Material (MCM)

Indications for Use *(Describe)*
The ADVIA Centaur® Progesterone (PRGE) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Progesterone assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143376

Device Name
ADVIA Centaur® Ferritin Master Curve Material (MCM)

Indications for Use *(Describe)*
The ADVIA Centaur® Ferritin (FER) Master Curve Material is for in vitro diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Ferritin assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary – ADVIA Centaur Progesterone Master Curve Material

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k143376

1. Applicant Information

Mailing Address: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA

Contact Person: Fatima Pacheco
Regulatory Clinical Affairs Specialist

Phone Number: (914) 524-2450
Fax Number: (914) 524-3579
E-mail Address: fatima.pacheco@siemens.com

Date Prepared: December 23, 2014

2. Device Name

Proprietary Name: **ADVIA Centaur® Progesterone (PRGE) Master Curve Material**

Measurand: Quality Control materials for ADVIA Centaur PRGE assay

Type of Test: Master Curve Material (MCM) for ADVIA Centaur PRGE assay

Regulation Section: 21 CFR 862.1660, Quality Control Material

Classification: Class I Reserved

Products Code: JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

Panel: Immunology (82)

3. Predicate Device Name IMMULITE/IMMULITE 1000 Progesterone Calibration Verification Material (CVM)

Predicate 510(k) No: k103683

4. Device Description: ADVIA Centaur® Progesterone Master Curve Material is an *in vitro* diagnostic product containing various levels of progesterone spiked in lyophilized human plasma with sodium azide (0.1%) and preservatives. Each set contains nine levels (MCM1–9); with a reconstituted volume of 1.0 mL/vial per

	level. MCM1contains no analyte. The MCMs assigned values are lot-specific of target values: 0.00, 1.20, 2.50, 5.00, 10.0, 20.0, 30.0, 42.0, and 65.0 ng/mL.
5. <u>Intended Use</u>: **Indication for Use:**	See Indications for Use Statement below: The ADVIA Centaur® Progesterone (PRGE) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Progesterone assay.
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	ADVIA Centaur® Systems
6. <u>Technological Characteristics and Substantial Equivalence Comparison with Predicate</u>:	A comparison of the device features, intended use, and other information demonstrates that the ADVIA Centaur PRGE MCM is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: *Substantial Equivalence Comparison*

SIMILARITIES		
	Candidate Device	**Predicate Device**
Item	ADVIA Centaur PRGE MCM	IMMULITE/IMMULITE 1000 Progesterone Calibration Verification Material (CVM)
Intended Use	The ADVIA Centaur Progesterone (PGRE) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Progesterone assay.	For *in vitro* diagnostic use, for the calibration verification of IMMULITE/IMMULITE 1000 Progesterone assay (LKPW).
Analyte	Progesterone	Same
Storage	2–8°C	Same
DIFFERENCES		
Use	Multiple Use	Single Use
Form	Lyophilized	Liquid
Matrix	Human plasma	Human serum
Levels	9	4
Stability	**Unopened** – Stable when stored unopened at 2–8°C for 6 months. **Opened (Reconstituted)** – Stable when stored at 2–8°C for 14 days; or on-board for 4 hours.	**Unopened** – Stable at 2–8°C up to the expiration date printed on the vial label. **Opened** – Stable at 2–8°C for 30 days.

7. Standard/Guidance Document References

The following recognized standard and guidance documents were used:

- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

8. Test Principle

The MCMs are specifically intended for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur assays for use on the ADVIA Centaur systems. Customers may use MCMs for bi-annual calibration verification checks of the assay range and linearity in order to meet the requirements of hospital accreditation bodies.

9. Performance Characteristics

9.1 Analytical performance:

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Analytical Specificity*
- *Assay cut-off*
- *Method Comparison Studies*
- *Clinical Studies (Sensitivity, Specificity, and cut-off)*

9.2 Non-Clinical Performance Testing

9.2.1 *Stability Studies*

Stability studies were conducted on the ADVIA Centaur XP system to support the shelf life (unopened) and reconstituted material for the ADVIA Centaur PRGE MCMs to ensure that it maintains optimal product performance throughout the established shelf-life. The data supports the stability claims detailed in the ADVIA Centaur PRGE MCM Instructions for Use.

The following stability studies were performed for ADVIA Centaur PRGE MCM:

- Real Time/Shelf Life (unopened) Stability
- In Use Open Vial (reconstituted) stored at 2–8°C Stability
- On-Board Stability

Real time shelf-life studies (unopened): Test PRGE MCMs were stored unopened at 2–8°C and tested at T=0 and at the following time points: 7 months and 10 months. Shelf life claims are based upon real time stability carried out one month after the duration claimed. Real time shelf-life stability studies of MCMs were determined by comparison of dose recoveries to -80°C reference MCMs. Current testing meets the sponsor's acceptance criteria for the real-time stability study up to the 7 months' time point, which supports a shelf-life claim of 6 months. Storage shelf-life (unopened) at 2–8°C is indicated by the expiration date on the vial label.

In-Use Open Vial (Reconstituted): Test PRGE MCMs were reconstituted, each level pooled, aliquotted and stored at 2–8°C, tested in 5 replicates per level at T=0, 2, 4, 7, 11, 14, and 15 days. Sponsor's acceptance criteria for the open vial (reconstituted) stability study were met to the 15 days' time point, which supports the open vial claim of 14 days when properly stored at 2–8°C.

On-board Stability: Pooled aliquots of test PRGE MCMs in sample cups were stored on the ADVIA Centaur XP system and measured at time point T=0, 2, 4 and 5 hours. On-board stability studies of MCMs were determined by comparison of dose recoveries to the T=0 dose recovery results. Sponsor's acceptance criteria for the on-board stability study were met up to 5 hours, which supports the on-board stability claim for 4 hours.

Stability Acceptance Criteria

The stability specifications acceptance criteria for the ADVIA Centaur PRGE MCM are as follows:

- Real Time/Shelf life (Unopened): The dose recovery for MCM1 must be ≤ 0.15 ng/mL dose; MCM2–9, the % dose recovery met the sponsor's required acceptance criteria.
- In-Use Open Vial (Reconstituted): The dose recovery for MCM1 must be ≤ 0.15 ng/mL dose; MCM2–9, the % dose recovery met the sponsor's required acceptance criteria.
- On-Board: The dose recovery for MCM1 must be ≤ 0.15 ng/mL dose; MCM2–9, the % dose recovery met the sponsor's required acceptance criteria.

9.2.2 *Value Assignment*

The ADVIA Centaur PRGE MCMs are value assigned using assigned reference calibrators and MCMs. The assigned reference calibrators are prepared using progesterone stock and are traceable to analytically prepared internal material which are traceable to gas-chromatography-mass spectroscopy (GC-MS). The MCMs are manufactured using qualified materials and measurement procedures.

Value assignment testing was conducted per the sponsor's value assignment procedure on the ADVIA Centaur XP system. The testing met the pre-defined sponsor's acceptance criteria. The new MCM doses must fall within the final value assignment specification for PRGE MCMs. The MCMs dose values are generated using the two-point calibration. The new MCM dose is calculated based on the relationship between the observed reference MCM dose and its assigned value. A performance verification run consisting of 6 replicates of each MCM level is run using one instrument, one reagent kit lot and Bio-Rad controls. The mean MCM doses of the new MCM lot manufactured must fall within the customer range specifications.

The target for MCM1 is assigned a 0.0 ng/mL dose. MCM1 is analyte-free basepool comprising of only the matrix and preservatives. The quality control specifications and final value assignment limits for PRGE MCM ensure that MCM1 measures at or below the PRGE assay sensitivity limit. MCM9 targeted greater than the assay range is diluted with the MCM1 to meet the reportable range of the assay.

9.2.3 *Expected Values*

The expected values are the lot-specific assigned values obtained at value assignment and the lot-specific assigned ranges are the lot-specific customer ranges established per the sponsor's internal procedural specifications for PRGE MCM.

ADVIA Centaur PRGE MCM levels and target values are provided in **Table 2.**

Table 2: *PRGE MCM Levels and Target Values*

MCM level	Target Values (ng/mL)
MCM1	0.00
MCM2	1.20
MCM3	2.50
MCM4	5.00
MCM5	10.0
MCM6	20.0
MCM7	30.0
MCM8	42.0
MCM9	65.0
Assay Range	0.21–60 ng/mL

9.2.4 *Traceability*

The ADVIA Centaur PRGE assay is standardized to an internal standard manufactured using Progesterone USP and traceable to gas chromatography-mass spectroscopy (GCMS). Assigned values for calibrators and MCMs are traceable to this standardization. The PRGE MCMs are manufactured using qualified materials and measurement procedures.

10. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

11. Conclusion

The ADVIA Centaur PRGE Master Curve Material (MCM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed IMMULITE/IMMULITE 1000 Progesterone Calibration Verification Material (CVM). Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur PRGE Master Curve Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

510(k) Summary – ADVIA Centaur Ferritin Master Curve Material

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k143376

1. Applicant Information	
Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 USA
Contact Person:	Fatima Pacheco Regulatory Clinical Affairs Specialist
Phone Number:	(914) 524-2450
Fax Number:	(914) 524-3579
E-mail Address:	fatima.pacheco@siemens.com
Date Prepared:	December 23, 2014
2. Device Name	
Proprietary Name:	**ADVIA Centaur® FER Master Curve Material**
Measurand:	Quality Control materials for ADVIA Centaur FER assay
Type of Test:	Master Curve Material (MCM) for ADVIA Centaur FER assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Immunology (82)
3. Predicate Device Name	Elecsys Ferritin CalCheck 5
Predicate 510(k) No:	k102267
4. Device Description:	ADVIA Centaur® Ferritin Master Curve Material is an *in vitro* diagnostic product containing various levels of ferritin in human serum with sodium azide. Each set contains eight levels; ready-to use (MCM1–8); with a volume of 1.0 mL/vial per level. MCM1 contains no analyte. The FER MCMs assigned values are lot-specific of target values: 0.00, 5.00, 10.5, 47.0, 150, 470, 800, and 1750 ng/mL.
5. Intended Use:	See Indications for Use Statement below:
Indication for Use:	The ADVIA Centaur® Ferritin (FER) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Ferritin assay.
Special Conditions for Use Statement(s):	For prescription use only

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Special Instrument Requirements:	ADVIA Centaur® Systems
6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the ADVIA Centaur FER MCM is substantially equivalent to the predicate device as summarized in **Table 1**.

Table 1: *Substantial Equivalence Comparison*

SIMILARITIES		
	Candidate Device	**Predicate Device**
Item	ADVIA Centaur Ferritin MCM	Elecsys Ferritin CalCheck 5
Intended Use	The ADVIA Centaur Ferritin (FER) MCM is for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur Ferritin assay.	The Elecsys Ferritin CalCheck5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Ferritin reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	Ferritin	Same
Storage	2–8°C	Same
Form	Liquid	Same
Matrix	Human Serum	Same
DIFFERENCES		
Use	Single Use	Multiple Use
Levels	8	5
Stability	**Unopened** – Stable when stored unopened at 2–8°C for 8 months. **Opened** – Stable when stored on-board for 4 hours.	**Unopened** – Stored at 2–8°C until the expiration date. **Opened** – Stable for 4 hours at 20–25°C.

7. Standard/Guidance Document References

The following recognized standard and guidance documents were used:

- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

8. Test Principle

The MCMs are specifically intended for *in vitro* diagnostic use in the verification of calibration and reportable range of the ADVIA Centaur assays for use on the ADVIA Centaur systems. Customers may use MCMs for bi-annual calibration verification checks of the assay range and linearity in order to meet the requirements of hospital accreditation bodies.

9. Performance Characteristics

9.1 Analytical performance:

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Analytical Specificity*
- *Assay cut-off*
- *Method Comparison Studies*
- *Clinical Studies (Sensitivity, Specificity, and cut-off)*

9.2 Non-Clinical Performance Testing

9.2.1 *Stability Studies*

Stability studies were conducted on the ADVIA Centaur XP system to support the shelf life unopened and open material for the ADVIA Centaur FER MCMs to ensure that it maintains optimal product performance throughout the established shelf-life. The data supports the stability claims detailed in the ADVIA Centaur FER MCM Instructions for Use.

The following stability studies were performed for ADVIA Centaur FER MCM:

- Real Time/Shelf Life (Unopened) Stability
- On-Board Stability

Real time shelf-life studies (unopened): Test FER MCMs were stored unopened at 2–8°C and tested at T=0 and at the following time points: 3 months, 7 months, 8 months, and 9 months. Shelf life claims are based upon real time stability carried out one month after the duration claimed. Real time shelf-life stability studies of MCMs were determined by comparison of dose recoveries to the -80°C stored reference MCM. Sponsor's acceptance criteria for the real-time stability study were met up to the 9 months' time point, which supports a shelf-life claim of 8 months. Unopened storage shelf-life is indicated by the expiration date on the vial label.

On-board Stability: Pooled aliquots of test FER MCMs in sample cups were stored on the ADVIA Centaur system and measured at time point T= 0, 2, 4 and 5 hours. Sponsor's acceptance criteria for the on-board stability study were met up to 5 hours, which supports the on-board stability claim for 4 hours.

Stability Acceptance Criteria

The sponsor's stability specifications acceptance criteria for the ADVIA Centaur FER MCM are as follows:

- Real Time/Shelf life (Unopened): The dose recovery for MCM1 must be ≤ 0.5 ng/mL dose; MCM2–8, the % dose recovery met the sponsor's required acceptance criteria.
- On-Board: The dose recovery for MCM1 must be ≤ 0.5 ng/mL dose; MCM2–8, the % dose recovery met the sponsor's required acceptance criteria.

9.2.2 *Value Assignment*

The ADVIA Centaur FER MCMs are value assigned using assigned reference calibrators and MCMs. The assigned reference calibrators are prepared using ferritin stock and are traceable to internal material that is standardized against World Health Organization (WHO) 2nd International Standard (WHO 80/578) reference material. The MCMs are manufactured using qualified materials and measurement procedures.

Value assignment testing was conducted per the sponsor's value assignment procedure on the ADVIA Centaur XP system. The testing met the pre-defined sponsor's acceptance criteria. The new MCM doses must fall within the final value assignment specification for FER MCMs. The MCMs dose values are generated using the two-point calibration. The new MCM dose is calculated based on the relationship between the observed reference MCM dose and its assigned value. A performance verification run consisting of 6 replicates of each MCM level is run using one instrument, one reagent kit lot and Bio-Rad controls. The mean MCM doses of the new MCM lot manufactured must fall within the customer range specifications.

The target for MCM1 is assigned a 0.0 ng/mL dose. MCM1 is analyte-free basepool comprising of only the matrix and preservatives. The quality control specifications and final value assignment limits for FER MCM ensure that MCM1 measures at or below the Ferritin assay sensitivity limit. MCM8 targeted greater than the assay range is diluted with the MCM1 to meet the reportable range of the assay.

9.2.3 ***Expected Values***

The expected values are the lot-specific assigned values obtained at value assignment and the lot-specific assigned ranges are the lot-specific customer ranges established per the sponsor's internal procedural specifications for FER MCM.

ADVIA Centaur FER MCM levels and target values are provided in **Table 2.**

Table 2: *FER MCM Levels and Target Values*

MCM Level	**Target Values (ng/mL)**
MCM1	0.00
MCM2	5.00
MCM3	10.5
MCM4	47.0
MCM5	150
MCM6	470
MCM7	800
MCM8	1750
Assay Range	0.5–1650 ng/mL

9.2.4 *Traceability*

The ADVIA Centaur Ferritin assay is standardized against the World Health Organization (WHO) 2nd International Standard (WHO 80/578) based on the following correlation:

WHO = 0.97 (ADVIA Centaur Ferritin) – 1.8 ng/mL, r=0.9

Assigned values for calibrators and MCMs are traceable to this standardization.

10. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

11. Conclusion

The ADVIA Centaur FER Master Curve Material (MCM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys Ferritin CalCheck 5. Based on the testing completed and the comparisons with predicate device, the ADVIA Centaur FER Maser Curve Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.